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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/944,234	10/06/1997	VINCENT BRYAN	A8038	1173

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EXAMINER

NGO, LIEN M

ART UNIT	PAPER NUMBER
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3727

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/944,234	Applicant(s) KUNZLER ET AL.	
	Examiner LIEN TM NGO	Art Unit 3727	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/22/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28, 30-50, 52-71, 73-85, 87-97, 99-102, 104-111, and 114-125 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 13-28, 30-50, 52-71, 73-85, 87-97, 99-102, 104-111, and 114-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/22/04 has been entered.

Specification

2. The amendment filed 12/4/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The original disclosure does not support the method of milling a vertebral body using the present invention drill head in paragraph [52]. Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the method (claim 62) is performed with the present invention device in which the device having a milling surface that has a profile that mates with the profile of the insert. In fact, the milling

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surface of the present invention in figs. 1-3 does not mate or look like the profile of the insert in figs. 6 and 7. Therefore, the method of perform invention must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 36, 37, 39-50, 52-66, 68, 77,78, 80-85, 87-96,110, 111, and 114-125 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example:

claims 37, "a smooth surface" is not supported in the specification.

claims 41, 47, 49, 62, 114, 120 and 121,"the milling surface has a profile which mates with the profile of the insert" is not supported in the specification.

Also in claim 41, "at least one milling surface being configured and oriented such that it is generally parallel to the surface having a predetermined contour created in the end plate of the adjacent vertebral body when in use" is not supported in the original specification.

claim 58, "said bearing surface is smooth" is not supported in the specification;

claims 36, 77, 93, 110 "at least two milling surfaces ... and end plate" is not supported in the specification;

also the steps in method claims 62, 64, 65 and 66 are not supported in the original speciation.

claims 68 and 80, "cutters includes first and second milling surfaces" is not supported in the specification.

claims 78, 82, 111 "a smooth surface" is not supported in the specification;

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claims 98, 112, 113, "at least two milling surfaces" is not supported in the specification.

claim 120, "cutter having a broad milling surface" is not supported in the specification.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 99 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 99 depends on canceled claim 98.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 5-7, 13-28, 30-50, 52-61 and 67-71, 73-85, 87-97, 99-102, 104-111, and 114-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheicher (4,197,645).

In regard to claims 1-3, 5-7, and 13-24, Scheicher discloses, in figs. 1-4 and 13-18, a milling apparatus or a device for preparing a space in human bone to receive an implant, which also is capable of preparing a space in a human spine to receive an insert if one desires to do so. Said milling apparatus comprises a drill head 11, a rotary form cutter 5, a drive means 40, elongate housing 3, said form cutter has a convex shape, a groove, and provided with a beveled gearing surface 37, the height of profile of the form cutter is approximately 9 mm, as disclosed in col. 17, line 56, said drive means having a pinion gear 39, and said cutter having a support shaft 8 which forms an angle approximately 96 degrees to the drive means 40, (angle approximately 96 degrees which generally could be 90 degrees).

The statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher which is capable of being used as claimed if one desires to do so, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In regard to claims 25-28, 30-50, 52-61 and 67-71, 73-85, 87-97, 99-102, 104-111, and 114 -125, Scheicher device disclose all limitations substantially as claimed, such as, the form cutter has at least one milling surface 5a, 5b, 5c (see figs. 1-3) that is

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capable to create a contour in one of the adjacent vertebral bodies; the gear 39 of the drive means is configured to mate with corresponding teeth 39 on the cutter (see figs. 5b, 13 and 14). Scheicher further discloses:

1. a form cutter is capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined surface shape ... wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies" (Claim 1), (see attached copies of figs. 2 and 3, which has been labeled by examiner)

2. wherein the rotary form cutter is capable to cut an imparted shape to the surfaces of the vertebral bodies that matches the predetermined shape of the endoprosthesis by rotation of the rotary form cutter" (in claim 18), (see attached copy of fig. 2);

3. said form cutter has at least one milling surface which is capable of being selected to create a surface contour in one of the adjacent vertebral bodies" (in claim 25), (see attached copy of fig. 2);

4. therefor, at least one milling surface is capable of creating at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies (in claim 41);

5. said form cutter has at least one milling surface is capable of being selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies (in Claim 47);

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6. said milling surface has a profile which mates with the profile of the insert to be implanted and a configuration adapted to remove bone from the vertebral bodies to prepare the vertebral bodies to receive the insert (in claim 49);

7. said form cutter having at least one milling surface is capable of being selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means" (in Claim 67);

8. said form cutter has at least one milling surface is capable of being selected to create a predetermined surface contour in one of the adjacent vertebral bodies (in claims 82, 97, 114, 120 and 121).

Response to Arguments

10. Applicant's arguments filed 4/22/04 have been fully considered but they are not persuasive.

Applicant traverses to the 35 U.S.C 112 rejections, first paragraph; however, that is not persuasive.

Regarding to claims 37 and 58, "a smooth surface" is not supported in the original specification. Applicant argues that "drawings alone may provide a 'written description' of an invention. However, figs. 1-3 of the present invention show only a part of the cross section of the housing surface 31; therefore, it cannot tell whether the whole surface as being smooth.

Regarding to claims 41, 47, 49, 62, 114, 120 and 121, "the milling surface has a profile which mates with the profile of the insert" is not supported in the specification.

Applicant argues that Scheicher does not teach the gear of the drive shaft configured to mate with teeth on the cutter; however, that is not found convincing because Scheicher discloses, in figs. 5b, 13 and 15, the gear 39 of the drive shaft configured to mate with teeth 37 of the form cutter.

Applicant argues that Scheicher does not teach the form cutter having at least one milling surface; however, that is not found convincing because Scheicher discloses, in figs. 1-3, the form cutter has at least one milling surface 5a, 5b, 5c, that is capable to create a contour in one of the adjacent vertebral bodies if one desires to use the Scheicher device to perform a milling in the vertebral body.

Applicant argues that the Office Action has improperly dismissed claim language because examiner has improperly refused to give weight to certain claim language in applying the teaching of Scheicher, both in the preamble and in the body of the claims, for example, in claim 25, "adjacent vertebral bodies, "at least one milling surface" is to create a surface contour. However, that is not found convincing because Scheicher discloses a drilling apparatus having a milling cutter for preparing bone cavities into which an endoprosthesis element can be inserted (see col. 1, lines 6-10), and the drilling apparatus comprises limitations substantially as claimed; therefore, it is capable of preparing a space having a surface contour in a human spine to receive an insert between adjacent vertebral bodies if one desires to do so.

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In response to applicant argument that the Scheicher does not necessarily possess the characteristic of the claimed invention in the Declaration of Mr. Calos Gil filed 4/22/04 because none of Scheicher devices includes 12 points of limitations in pages 1 and 4 of the Declaration, examiner has pointed out Scheicher devices including all limitations as claimed in the rejection above. Moreover,

the statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Scheicher discloses a milling apparatus for preparing a space in human bone to receive an implant comprising limitations substantially as claimed, therefore, the Scheicher milling apparatus is capable of preparing a space in a human spine to receive an insert if one desires to do so.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIEN TM NGO whose telephone number is 703-305-0294. The examiner can normally be reached on Monday through Friday from 8:30 AM -6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LEE YOUNG can be reached on 703-308-2572. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lien Ngo

July 20, 2004



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